PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

McMASTER OBERIN ARTHUR ROBINSON &
HEDDERWICKS
GPO BOX 1776Q
MELBOURNE VIC 3001

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
day/month/year 15 SEP 2000

Applicant's or agent's file reference
110290

IMPORTANT NOTIFICATION

International application No.	International filing date	Priority date
PCT/AU99/00726	3 September 1999	4 September 1998

Applicant
WOLFE RESEARCH PTY LTD et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	MICHAEL C. LANDER Telephone No. (02) 6283 2494

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 110290	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU99/00726**	International filing date *(day/month/year)* 3 September 1999	Priority Date *(day/month/year)* 4 September 1998
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61B 5/05, A61F 2/04, A61F 2/48, A61M 29/00		
Applicant WOLFE RESEARCH PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand 29 March 2000	Date of completion of the report 31 August 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer MICHAEL C. LANDER Telephone No. (02) 6283 2494

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU99/00726

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

International application No.
PCT/AU99/00726

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 25

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 25

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

International application No.
PCT/AU99/00726

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-24	YES
	Claims		NO
Inventive step (IS)	Claims	1-24	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

WO 98/29030;
US 5735887; and
US 5769875.

Novelty (N) Claims 1-24

All the documents cited in the ISR were category A only. Therefore the claimed invention is not disclosed in any of these patent documents and hence all the claims are novel.

Inventive Step (IS) Claims 1-24

The claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

McMASTER OBERIN ARTHUR ROBINSON &
HEDDERWICKS
GPO BOX 1776Q
MELBOURNE VIC 3001

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	26 April 2000
Applicant's or agent's file reference 110290	**REPLY DUE** within **TWO MONTHS** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU99/00726	3 September 1999	4 September 1998

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. [7] A61B 5/05, A61F 2/04, A61F 2/48, A61M 29/00

Applicant

WOLFE RESEARCH PTY LTD et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:.

I	[X]	Basis of the opinion
II	[ ]	Priority
III	[X]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **4 January 2001**

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**MICHAEL C. LANDER** Telephone No. (02) 6283 2494

WRITTEN OPINION

International application No.
PCT/AU99/00726

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claim No: 25 .

because:

☐ the said international application, or the said claim Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 25

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

WRITTEN OPINION

International application No.
PCT/AU99/00726

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-24	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	1-24	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	1-24	**YES**
	Claims		**NO**

2. Citations and explanations

The following documents identified in the International Search Report have been considered for the purposes of this report:

WO 98/29030;
US 5735887; and
US 5769875.

Novelty (N) Claims 1-24

All the documents cited in the ISR were category A only. Therefore the claimed invention is not disclosed in any of these patent documents and hence all the claims are novel.

Inventive Step (IS) Claims 1-24

The claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00726

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 5/05, A61F 2/04, A61F 2/48, A61M 29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61#

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT, IBM Patent Database

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98/29030 (Johnson & Johnson Research) 9 July 1998 See whole document.	1-24
A	US 5735887 (Barreras, Sr. et al.) 7 April 1998 See whole document.	1-24
A	US 5769875 (Peckham et al.) 23 June 1998 See whole document.	1-24

☐ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 October 1999	11 OCT 1999
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer **Michael C Lander** Telephone No.: (02) 6283 2494

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00726

Box 1 Observations where certain claims were found unsearchable (Continuation f item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 25
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

The scope of the claim is indeterminate.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00726

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member		
WO 98/29030	AU 53386/98	CA 2247943	EP 904009
	IL 125932		
US 5769875	US 5776171		

END OF ANNEX

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 110290	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU99/00726**	International filing date *(day/month/year)* 3 September 1999	Priority Date *(day/month/year)* 4 September 1998

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61B 5/05, A61F 2/04, A61F 2/48, A61M 29/00

Applicant

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III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
29 March 2000	31 August 2000
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**MICHAEL C. LANDER** Telephone No. (02) 6283 2494

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU99/00726

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
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pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

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These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

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4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: **25**

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. **25**

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**1-24**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-24**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-24**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

WO 98/29030;
US 5735887; and
US 5769875.

Novelty (N) Claims 1-24

All the documents cited in the ISR were category A only. Therefore the claimed invention is not disclosed in any of these patent documents and hence all the claims are novel.

Inventive Step (IS) Claims 1-24

The claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

M.H

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61B 5/05, A61F 2/04, 2/48, A61M 29/00 | **A1**

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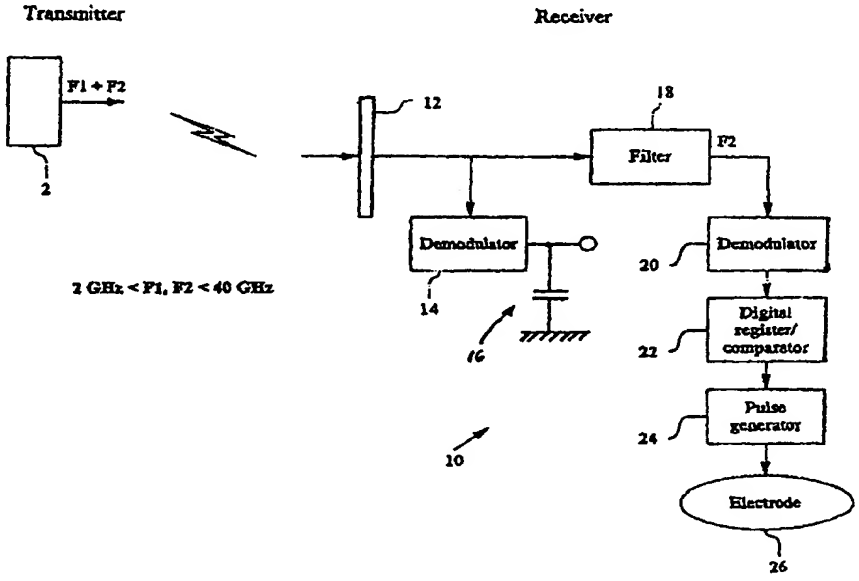

(57) Abstract

There is provided a system for transmission of power and/or information between a first location external of a living body and a second position internal of the living body which comprises: (a) a primary controller (2) comprising a power source and a transmitter locatable at the first locations; and (b) an antenna (12) based device (10) locatable at the second position to receive an output from the transmitter, wherein the power source is adapted to emit high frequency electromagnetic radiation between 0.5 to 5 GHz. A medical appliance comprising a spring–based stent incorporating a monitoring device wherein the spring of the stent acts as the aerial for the monitoring device and wherein the medical appliance is capable of receiving electromagnetic radiation with a frequency between 0.5 to 5 GHz.

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MEDICAL IMPLANT SYSTEM

Field of the Invention

The invention relates to a system which facilitates monitoring, treatment and stimulation of a living body. More particularly, this system relies upon the use of electromagnetic waves as the means of transmission of energy and signals between a device implantable inside the living body and an external control device.

The invention, in a separate embodiment, also relates to a device that may be implanted inside the cardiovascular system so that properties of the environment within the body at which it is implanted may be monitored and a blood flow passage can be enlarged. The device is electrically powered and controlled by an external source of electromagnetic radiation.

Background to the Invention

Whilst the following description is in terms of particular applications eg. muscle stimulation and the use of stents, it is to be understood that the invention has wider application.

A number of people all over the world lose their natural ability to control their muscle contraction and are thus physically disabled. Functional Electrical Stimulation (FES) is a technique which incorporates the stimulation of muscles for providing functionality to people suffering from neuromotor control disorders or have otherwise lost their natural ability to control and contract their muscles usefully. The disorder or loss of natural ability can arise through a range of causes, including disease, trauma or stroke.

FES devices can be classified into two categories - implants and external. External FES devices include simple devices such as those used to correct drop foot, and have been in use for a few decades. The implantable devices are relatively new and the first commercialisation of such a device took place in 1997.

In the present art, implantable devices consist of a controller and a set of up to 16 electrodes connected by wires which run inside the body (Memberg, Peckham, Keith, "A Surgically Implant Intramuscular Electrode for An Implantable Neuromuscular Stimulation System", IEEE trans.Rehab.Eng, vol. 2, no.2, Jun 1994). In this art, the device does not

have any internal power source but it is powered by an oscillating magnetic field from the power source coupled with the secondary pick up coil implanted within the patient as a component of the device.

FES devices have been reported which provide this format (US Patent No. 5,358,514 to Schulman et al; Matjacic et al "Wireless Control of Functional Electrical Stimulation Systems", PMnD:9148704, UI:97205715; Sawan, Hassouna et al "Stimulator Design and Subsequent Stimulation Parameter Optimization for Controlling Micturition and Reducing Urethral Resistance", IEEE trans. Rehab.Eng., vol.4, no.l, Mar 1996). In these devices, each of the muscle stimulating electrodes is addressable individually. The devices reported have employed frequencies of the magnetic field between 400 K Hz to 50 M Hz.

It is an intrinsic limitation of such magnetic technologies that the source of the oscillating magnetic field must be close to the pick up coil to efficiently transfer energy by inductive coupling of the magnetic field of the exciting source and the implanted magnetic coil receiver.

Some FES systems reported in the prior art provide the forward loop control for the muscles. Devices have been designed which record information from the extremities - either by recording neural activity or by using sensors (like pressure or vibration etc.) and feedback this information to the controller (Haugland, Hoffer et al "Skin Contact Force Information in Sensory Nerve Signals Recorded by Implanted Cuff Electrodes", IEEE trans.Rehab.Eng.,vol.2, no.l, Mar 1994). Some difficulties associated with these techniques are the invasive nature of their implementation and that further the information received is unnatural so the subjects have to learn to react to this information.

Available devices like the Drop Foot FES system automatically restore the gait of the subject and are not under the conscious control of the subject. FES systems like grasp control devices and other similar systems work under the linear control of the subject. These latter devices have a number of drawbacks including the need for total visual attention of the subject which restricts the application of the device. Another drawback is the fact that these devices are not intelligent, unlike the body which has a Peripheral Neuromotor control mechanism which works along with the Central Neural System (CNS). Thus subjects fitted with the FES devices have to use their CNS to monitor and control the muscle contraction.

A number of researchers have proposed systems which provide feedback to the subjects (Haughland, Hoffer et al, "Skin Contact Force Information in Sensory Nerve Signals Recorded by Implanted CuffElectrodes", IEEE trans. Rehab. Eng. vol.2, no. 1, Mar 1994; Hoffer JD, "Closed Loop, Implanted Sensor, Functional Electrical Stimulation System for Partial Restoration of Motor Functions", US Patent No. 4,750,499). These systems primarily utilise invasive methods like recording the neural activity, embedding sensors inside the body or fixing them on the surface of the body. These techniques are highly invasive and also restrictive to the subjects.

Another known method for muscle stimulation is multi-channel surface FES systems wherein the electrodes are supported on electrode trousers (Mayr, W et al "EMG-controlled adjustment and fatigue monitoring in multi-channel surface stimulators" Proceedings of the Second Annual IFESS Conference (IFESS'97) and Neural Prosthesis: Motor Systems 5 (NP'97) pages 13-14). Continued investigations, such as this, into external stimulation methods is a result of the above disadvantages of internal systems.

Accordingly, investigations were carried out to simplify these known highly invasive techniques. In particular, it was felt that if an alternative method could be developed to communicate between the external control and the internal devices, it may be possible to avoid or limit the use of wires in the body, in particular, to avoid the medically dangerous situation where wires penetrate a membrane such as the skin, intestinal walls or arterial walls. The desired alternative method would also permit monitoring, treatment and stimulation devices to be placed deeper and more locally to the area of interest in the body.

Various attempts to provide suitable systems and devices have been proposed. The following patents and patent applications disclose some of these attempts.

United States patent no. 5,314,458

The implantable microstimulator system employs a miniature ferrite-cored coil contained within a hermetically sealed housing to receive control signals and operating power from an RF telemetry system. The tiny coil receives the electromagnetic energy which is transmitted from a non-implantable transmitter which generates a code-modulated carrier. Demodulator circuitry in the implantable microcircuit is employed to extract the control information, while applying the electromagnetic energy to power the electronic circuitry

therein and charge a capacitor which will provide the electrical stimulation to the living being. The electrical stimulation is delivered by a stimulating electrode which has a waffle-like configuration whereby a plurality of iridium oxide electrode pads, coupled in parallel, so as to be characterised by a long effective edge distance, transfer the stimulating charge. The electrical components of the microstimulator are contained within a hermetically sealed housing formed of a glass capsule which is electrostatically bonded to a silicon substrate.

United States patent no. 5,735,887

The citation discloses an implantable, electrically operated medical device system comprising an implantable radio frequency receiver and an external radio frequency transmitter. The system is a closed-loop, inductively coupled radio frequency energy transfer system whereby the transmitted radio frequency power is adjusted up or down by the receiver as a function of received vs. required power, via commands up-linked by the receiver to the transmitter. The subcutaneous receiver incorporates the required faculties to autonomously control all stimulation parameters after it has been programmed only once. The stimulation parameters controlled by the receiver are pulse amplitude, width and frequency, plus identification of the electrodes to be enabled and their respective polarity.

United States patent no. 5,769,875

This citation discloses a functional neuromuscular stimulation system. The system includes an implanted unit which is powered by the carrier frequency of the transmitted signal and stimulation pulse train decoders. The preferred embodiment uses a frequency of about 10 MHz.

European patent application no. 0 343 858

This citation discloses a telemetry system which comprises an implantable element having temperature dependent NMR properties, apparatus for applying a radio frequency field to the implantable element, and apparatus for sensing the temperature dependent NMR resonance response of the implantable element and for providing an output indication of temperature of the implantable element. The aim of the citation is to provide a wireless thermometry system useful in clinical hyperthermia. There is disclosure of the implantable elements including a rare earth metal which determines the resonance frequency to be used.

As an example, yttrium is said to resonate at approximately 53.578 MHz (0.0535 GHz) at 30 degrees C.

US patent no. 3,662,758 discloses a telemetric system which operates at 350 kilocycles. A unit is implanted in the body which is powered by a source external of the body. The unit senses resistance between two electrodes inside the body and encodes the resistance as a frequency modulated signal which is then transmitted to a receiver outside of the body.

US patent no. 3,727,616 discloses a telemetric system which operates at 100 KHz. A receiver totally implanted within a living body is inductively coupled by two associated receiving coils to a physically unattached external transmitter which transmits two signals of different frequencies to the receiver via two associated transmitting coils. One signal provides commands to the receiver and the other signal provides a power source.

US patent no. 4,524,774 discloses a telemetric system which operates at 40.68 to 40.75 MHz. The system includes muscle potential sensors, muscle stimulators and a transmitter-receiver which receive and transmit signals via antennae without being wired to each other.

US patent no. 4,102,344 discloses a telemetric system which operates at 300 KHz. The implantable unit has an energy storing device connected to electrodes under the control of a transistor which is normally maintained non-conductive as a result of the voltage drop across an impedance connected to the power supply so that each time the power supply is interrupted the transistor becomes conductive to discharge the energy storage device through the electrodes.

US patent no. 4,494,950 discloses a telemetric system which operates at 10-50 KHz. The system consists of a multiplicity of separate modules which collectively perform a useful biomedical purpose; the modules communicating with each other without the use of interconnecting wires. The modules may be intracorporeal or extracorporeal. Physiological sensor measurements sent from a first module caused a second module to perform some function in a closed loop manner.

US patent no 4,561,443 discloses a telemetric system which operates at frequencies of 51.2 KHz and 48.0 KHz. A two way coherent inductive communications link between an external transceiver and internal transceiver is disclosed which transmits digitally formatted data by frequency shift keying the inductive communications link. Further immediate

verification of establishment of a reliable communications link is provided by determining the existence of frequency lock and bit phase lock between external and internal transceivers.

US patent no. 4,628,933 discloses a visual prosthesis for implanting in an eye which is powered by telemetry. The prosthesis has a close-packed array of photosensitive devices on one surface thereof. There is disclosure of placing the transmitter about an eyeglass frame lens opening, so that the axis of the transmitting coil is oriented directly toward and in alignment with the axis of the coil.

US patent no. 4,741,339 discloses a means to improve the electromagnetic coupling between the transmitter and receiver in a telemetric system by using a further coupling coil. The system requires the transmitter and receiver to be close proximity.

US patent no. 4,932,405 discloses a telemetric system which operates at a frequency between 100-500 KHz. The system disclosed is for stimulating a nerve or muscle fibre, especially a hearing nerve in the cochlea. The system includes an implant and electrode for stimulating the nerve which is connected to the implant. The system is powered by a small transformer wherein one coil is implanted and the other is external but in the vicinity of the implanted coil. For supplying information to the implant, infrared transmissions are used wherein the transmitter is provided adjacent to the skin and the receiver on the outside of the body.

US patent no. 5,070,535 discloses a telemetric system designed to improve coupling efficiency between external transmitter and internal receiver. The citation requires that that receiver and transmitter be in very close proximity.

With the exception of US patent 5,314,458, all of the devices in the above prior art rely on inductive coupling to transfer the energy and are therefore limited in their applications because they must be implanted close to the surface of the body in order to receive the signals from the primary control. The device is US patent 5,314,458 receives electromagnetic radiation of a low frequency (that is, well below 0.5 GHz) and is a bulky device as a result of this low frequency.

There is also a well known art of medical appliances in the form of cylindrical shape with a wire cage called stents. These stent devices have been developed to enable cardiovascular

surgeons and cardiologists to introduce these as part of their treatment to aid healing or relieve an obstruction. The stents are usually initially provided in a collapsed form on an inflatable support. In this form they are introduced into an appropriate blood vessel, such as the femoral artery near the groin, and carefully moved to the site of restricted blood flow. The supporting balloon is then inflated so deforming the stent spring structure to press outwards into the wall of the blood vessel. The implanting apparatus and the inflatable support is then withdrawn, leaving the expanded stent to maintain the blood vessel open and allow improved blood flow.

It is further desired to combine a stent and a monitoring and/or stimulating device. In this way, it would be possible to continuously monitor the operation of the heart and provide information to assist preventative therapies to be adopted by a person.

One attempt to combine a stent with a monitoring device is described in PCT application WO 98/29030. This application discloses a stent device which incorporates a device for measuring the fluid flow in the body of the person. The device for measuring blood flow transmits the measurement results to a receiver outside the body.

In one example of this, the stent has a resilient coil made of electrically-conductive material and coupled at both ends to circuitry associated with the flow parameter sensor and/or the transmitter. The energy source outside the body generates a time-varying magnetic field within the vicinity of the coil, which field is preferably aligned with a central axis thereof, this causing an electrical current to flow in the coil and provide energy to the flow parameter sensor and/or transmitter.

The system uses a magnetic coil to create a magnetic field so that a potential is created at right angles to the magnetic field and proportional to the flow rate.

From the formula on page 20 of the citation, the frequency transmitted is about 0.8 MHz which is a low frequency. Again the low frequency gives rise to a bulky device. Further, the ECG recorder is separate from the stent and has sensor electrodes which are externally placed onto the skin rather than implanted.

Description of the Invention

It has now been found that there is a range of appropriate frequencies within the electromagnetic spectrum where the radiation penetrates flesh effectively. This permits the

transmitter to be separated a convenient distance from the receiver that is many times the separation permitted by known coupled magnetic fields.

Accordingly, there is provided a system for transmission of power and/or information between a first location external of a living body and a second position internal of the living body which comprises:

(a) a primary controller comprising a power source and a transmitter locatable at the first location; and

(b) an antenna based device locatable at the second position to receive an output from the transmitter,

wherein the power source is adapted to emit high frequency electromagnetic radiation between 0.5 to 5 GHz.

In particular, the preferred range of high frequency electromagnetic radiation is 0.8 to 2.5 GHz. This high frequency electromagnetic radiation is receivable by the antenna on the implanted device and used as a source of electrical energy to power the device as well as being capable of carrying an information signal to operate the implanted device.

It was surprisingly found that the use of high frequency electromagnetic radiation between 0.5 to 5 GHz allows significant spatial separation of the primary controller and the implanted device. As such it potentially avoids wires to implanted devices such as stimulating electrodes and permits a number of devices to be implanted deep in the body.

Further, the use of radiation at this frequency removes the need to use coils in the antenna based device because there is no inductive coupling.

It was also found that these high frequencies permitted the use of antennae that were small enough to conveniently implant but still to permit significant penetration of the electromagnetic energy into the body. The antenna format could be, for example, a simple dipole, a loop with or without crenellations, or a microstrip antenna including slot and patch formats. The preferred alternative is a planar omnidirectional format that is integrated into the construction of the device.

Preferably, the primary controller may comprise other devices, for example, a receiver to receive data from the implanted device. In this respect, the implanted device may be used

to sense properties of its environment and then transmit such data as electromagnetic radiation to the receiver.

Accordingly, it is preferred for the antenna based device to comprise means to monitor predetermined conditions adjacent the antenna based device and to emit signals representative of one or more of these conditions to be received by the primary controller. By way of illustration only, the device may:

(a) measure the activity of the heart in terms of a electrocardiogram; and

(b) transmit this information to the primary controller.

In this way, it is possible to continuously monitor the operation of the heart and provide information to assist preventative therapies to be adopted by a person.

It is also preferred that the antenna based device may itself be a medical appliance which could operate in response to the transmitted signal. For example, the antenna based device could be a stent which is spring based where the spring acts as the antenna. This device may also be used to derive the data needed to register an electrocardiogram as described above.

According to yet another preferred form, the antenna based device may comprise means to generate pulses of current. By way of illustration only, the device may:

(a) take the transmitted signal, send out pulses for muscle stimulation as specified by the signal regulating commencement time, pulse width, pulse frequency and number of pulses;

(b) measure electrocardiogram (ECG), pCa, glucose, pO_2, pNa, electromyogram (EMG), pH, muscle dimensions and transmit this data to the primary controller;

(c) be a combination of features (a) and (b);

(d) measure the Electroencephalogram inside a cranium to detect abnormal brain conditions such as epilepsy and transmit a signal to the primary controller to activate an alarm;

(e) send out suitable pulses in response to the condition sensed in (d) to trip the brain action back into normal activity.

According to a second aspect of the invention, there is provided a method for transmitting power and/or information between a first location external of a living body at which a primary controller comprising a power source and a transmitter is located, and a second location inside the living body at which an antenna based device is located, the method comprises the steps of:

(a) generating high frequency electromagnetic radiation between 0.5 to 5GHz from the power source and emitting that radiation from the transmitter of the primary controller; and

(b) receiving the radiation at the antenna based device.

In particular, the preferred range of the high frequency electromagnetic radiation is 0.8 to 2.5 GHz.

Preferably, the method comprises the further steps of:

(c) powering the antenna based device with the radiation; and/or

(d) causing the antenna based device to generate and emit pulses of current; and/or

(e) monitoring predetermined conditions adjacent to the antenna based device and emitting signals representative of one or more of these conditions to be received by the primary controller.

It has also been found that a stent and a monitoring device may be combined into a single unit thereby achieving two objectives with one operation. Further, the combined device resembles a standard stent, and therefore may be implanted into the patient using the same procedure as for a standard stent.

According to a third aspect of the invention, a medical appliance is provided which comprises a spring-based stent incorporating a monitoring device wherein the spring of the stent acts as the aerial for the monitoring device and wherein the medical appliance is capable of receiving electromagnetic radiation with a frequency between 0.5 to 5 GHz.

Preferably, the monitoring device is located in the support of the stent. Preferably, the monitoring device works in conjunction with a primary controller. The monitoring device will preferably comprise means to monitor predetermined conditions in the vicinity the

medical appliance and means to emit signals representative of one or more of these conditions to be received by the primary controller.

Preferably, the primary controller is separate and located outside the body in which the stent is implanted. Preferably, the primary controller is adapted to emit high frequency electromagnetic radiation between 0.5 to 5 GHz. This is particularly useful for deep implants. Preferably, the primary controller is a power source for the monitoring device.

In situations where it is difficult to communicate directly with the medical appliance, a second intermediate implant may be necessary which is closer to the skin surface and which can relay the power and instructions from the primary controller to the medical appliance.

Detailed Description of the Invention

Whilst the following discussion is in terms of using the above system and method for stimulation purposes, it will be understood from the discussion above that the invention is not so limited. The invention provides a system of interaction between a location outside the living body and a location inside the living body which permits power and/or information to flow therebetween. The nature of the information and use of power will depend upon the antennae based device implanted in the living body.

In a first example of the invention, there is provided a stimulation device for providing artificial electrical stimulation comprising a receiver antenna for receiving electromagnetic radiation ranging from between 0.5 to 5 GHz from a primary controller, a supply circuit for deriving electrical energy from the received electromagnetic radiation, an isolating circuit for isolating data signals from the received electromagnetic radiation, a pulse generator for generating electrical pulses according to the data signals utilising the electrical energy from the supply circuit, and a stimulating electrode for outputting the electrical pulses from the pulse generator.

In other words, this stimulation device comprises an antenna for receiving electromagnetic radiation in the range between 0.5 to 5 GHz from a primary controller and converting it to an oscillating current, a converter for converting the oscillating current to an electrical supply suitable to provide power for the device, an isolating circuit for separating a data

signal from the oscillating current, and a pulse generator activated according to the data signal to provide electrical stimulation pulses using said electrical supply power

The stimulation device may therefore be at least substantially encapsulated in a biocompatible material, such as a suitable epoxy, silicone polymer, "diamond" coating or the like. The stimulating electrode can be constructed from a suitable biocompatible conductive material, such as titanium, surgical stainless steel, gold, osmium, iridium and platinum. The components of the stimulation device may be contained in a single substantially encapsulated unit for ease of surgical implantation, however it is possible that the antenna and/or electrode be separate and connected to the remainder of the device by way of a short wire, for example. This construction may be desirable where the site to be stimulated by the device (i.e. the desired position of the electrode) is located relatively deep within the subject tissue. The concept of the invention would permit the antenna to be near the tissue surface for reduced attenuation of the electromagnetic radiation received at the antenna. It may additionally be desirable to provide a coating or patch of an anti reflection material on the tissue surface over the antenna to further reduce electromagnetic radiation signal attenuation.

In another example of the invention, a plurality of stimulation devices are used and are responsive to signals from a single primary controller. In this case, it is desirable for each stimulation device, or groups of stimulation devices, to be selectively actuated by the received data signals. Accordingly, the isolating circuit or pulse generator is preferably constructed to be addressable by certain data signals, such that stimulation pulses are only generated if a certain form of data signal is received from the primary controller. For example, the stimulation device can be constructed to decode modulated digital codes and compared with predetermined codes to ascertain whether that particular device is being addressed. Alternatively, a form of frequency signal coding can be used, and the isolating circuit adapted to isolate only the data signals intended for that device. Other data encoded in the data signals can be utilised by the pulse generator to control the characteristics of electrical pulses generated, such as pulse shape, magnitude, duration and frequency.

Most patients require several devices to stimulate various muscles and sense their condition and this may be achieved by the central primary controller sending the signals that contain

addresses of the particular electrodes to be activated or the transmitted data contains related addresses.

For example, this invention allows the patient to have the many electrodes required to stimulate walking without the fragile wires crossing joints.

According to a further embodiment of the invention, there is provided an artificial muscle stimulation system comprising at least one stimulating electrode for providing artificial electrical stimulation to a muscle under control of a primary controller capable of transmitting high frequency electromagnetic radiation between 0.5 to 5 GHz, an EMG sensor for measuring EMG signals from the muscle during stimulation, a neural network processor coupled to receive the measured EMG signals to extract information regarding force of contraction and fatigue of the muscle, and wherein the primary controller is coupled to an output of the neural network processor to control said artificial electrical stimulation based on said extracted information.

It has been discovered that particular muscles rapidly tire if stimulated incorrectly but this may be avoided if the muscle is stimulated in different regions or less frequently. The art of stimulating muscles requires careful monitoring of several aspects to avoid tiring. It has been discovered that the EMG of the working muscle can be used to characterize the onset of tiring as can extension over time, pressure of the muscle during contraction and the pH of the tissue of the muscle. The primary controller then varies the stimulation to accommodate the tiring muscle.

It is well known that muscle fatigue is associated with the production of lactic acid rather than carbon dioxide and this is monitored by measuring the pH and pO_2 of the muscle. Similarly, with the medical appliance of the third aspect of the invention, it is valuable to measure the glucose concentration and pO_2 as the onset of aschemia in a diabetic is indicated when the glucose is high and the pO_2 is low. This indication with the ECG is useful for diagnosis of a potentially dangerous condition of the patient.

In an embodiment of the third aspect of the invention, the wire spring structure of a stent performs the known basic function of expanding blood vessels, and can also conduct electrical signals and thereby act as the antenna for receiving electromagnetic energy. The small diameter of blood vessels and the reduction in wavelength caused by the high

permittivity of blood and blood vessel wall, requires that the frequency of the electromagnetic radiation be greater than 0.5 GHz. It has been surprisingly found that electromagnetic radiation up to for example, a frequency of 1.7 GHz can be usefully transmitted to an antenna that is implanted inside a blood vessel and immersed in blood. The high frequency electromagnetic radiation causes a typical oscillating current in the wire of the stent and this current may be modified by designing the inductance and capacitance of the wire structure to induce resonance. The resulting current is rectified and used to power the monitoring device.

The direct current is then used to charge either a capacitor or miniature battery. Typically, the circuit would be a low power microprocessor with both A/D ("analogue/digital") inputs and output drivers suitable for generating the pulse train to be applied to the antenna for transmission out of the body. For simple versions of the technology, the function of the microprocessor would be replaced by discrete or partially integrated circuits that perform the function of processing the signals from the sensor, analysing the signal then transmitting the alarm signal.

In this arrangement, the electronics are typically used to monitor the electrocardiogram but may also monitor pH, blood flow, pCa and other metabolites. The device also has provision to transmit signals out of the body, typically to give an alarm for an abnormal condition.

In one practical form of the invention, the stent is configured as stiff hoops to expand blood vessels but the surgical procedure requires that they be implanted in a collapsed form. Each hoop is pleated with the pleats roughly sinusoidal so that the amplitude of the sinusoid is normal to the plane of the hoop so making the sinusoidal in the same cylindrical plane as the wall of the blood vessel in which is implanted. The pleating is controlled in amplitude and number of pleats to give a radiation impedance for the antenna similar to the space impedance of the body environment. Similarly, the pleating also gives some control over the inductance and capacitance of the antenna considered as a resonant tank circuit together with the characteristics of the rectifier.

Examples

The invention will now be further explained and illustrated by the following non-limiting examples.

Examples 1 to 4 investigate the fabrication of antennae which will receive radiation with a frequency between 0.5-5 GHz.

Example 1

A microwave patch antenna 17 by 17 mm area with a separating dielectric of relative permittivity 10.2 and 1.905 mm thickness was fabricated, coated with Dow Corning Silicone polymer and placed inside a moist piece of fatty tissue/skin at a depth of 10 mm. The antenna was excited with electromagnetic radiation of 500 milliwatts from a transmitter and the frequency varied near 2.5 GHz to establish the optimum resonant frequency. The power received at the antenna was measured using a microwave power meter when the transmitter was at 12 and 50 cm and found to be 10 mW and 1.6 mW and at 12cm the output of the antenna was recitified with a full wave bridge and showed a voltage of 2.5 volts.

Example 2

A microwave patch antenna 29 by 29 mm area with a separating dielectric of relative permittivity 10.2 and 1.905 mm thickness was fabricated, coated with Dow Corning Silicone polymer and placed inside a moist piece of fatty tissue/skin at a depth of 10 mm. The antenna was excited with electromagnetic radiation of 500 milliwatts from a transmitter and the frequency varied near 1.5 GHz to establish the optimum resonant frequency. The power received at the antenna was measured using a microwave power meter when the transmitter was at 12 and 50 cm and found to be 25 mW and 3.2 mW and at 12cm the output of the antenna was rectified with a full wave bridge and showed a voltage of 2.3 volts. The thickness of the fatty tissue was then increased to 20mm and the test repeated and showed at 50 cm a power output of 2.5 mW and at 100 cm a power output of 0.4 mW.

Example 3

A microwave patch antenna 33 by 33 mm area with a separating dielectric of relative permittivity 2.2 and 1.58 mm thickness was fabricated, coated with Dow Corning Silicone polymer and placed inside a moist piece of fatty tissue/skin at a depth of 10 mm. The antenna was excited with electromagnetic radiation of 500 milliwatts from a transmitter and the frequency varied near 2.5 GHz to establish the optimum resonant frequency. The power received at the antenna was measured using a microwave power meter when the transmitter was at 12 and 50 cm and found to be 10 mW and 0.8 mW and at 12cm the output of the antenna was rectified with a full wave bridge and showed a voltage of 2.6 volts.

Example 4

A microwave patch antenna 60 by 60 mm area with a separating dielectric of relative permittivity 2.2 and 1.56 mm thickness was fabricated, coated with Dow Corning Silicone polymer and placed inside a moist piece of fatty tissue/skin at a depth of 10 mm. The antenna was excited with electromagnetic radiation of 500 milliwatts from a transmitter and the frequency varied near 1.5 GHz to establish the optimum resonant frequency. The power received at the antenna was measured using a microwave power meter when the transmitter was at 12, 50 and 100 cm and found to be 25 mW, 6.3 mW and 0.8 mW and at 12cm the output of the antenna was rectified with a full wave bridge and showed a voltage of 2.8 volts. The thickness of the fatty tissue was then increased to 20mm and the test repeated and showed at 50cm a power output of 3.2 mW and at 100cm a power output of 0.25 mW.

Summary

Examples 1 to 4 illustrate that radiation with a frequency between 0.5-2.5 GHz can be used to generate power in an antenna based device without the need for inductive coupling.

In Examples 5 to 8 investigations were conducted into the fabrication of devices which could be used in a medical device according to the third aspect of the invention.

Example 5

Surgical stainless steel wire 316LVM and diameter 0.0059 in. was pleated with a sinusoid of amplitude 0.039 in. giving five cycles in 0.83 in. This planar structure was then bent to form a hoop and attached to a Schottky diode and measuring apparatus. The entire assembly was coated with a biodegradable resin such as silicone polymer to provide electrical insulation from the biological fluids.

The device was implanted in the artery of a bovine liver and irrigated with heparinised blood. The entire assembly was then transferred to a chamber for testing microwave transmitters and irradiated with electromagnetic energy that was varied in frequency between 0.5 GHz and 2 GHz and the energy received monitored. This test showed satisfactory energy was received up to a frequency of 1300MHz, with several peaks including 850 MHz, and gave an output of 1.5 volts and 400 microwatts when immersed in blood and excited.

It would be understood that a variety of types of wire are useful including titanium and metals in the platinum group, and the wire may have coatings to reduce energy loss by conduction through the body electrolyte and improve the acceptance of the device by the body immune system. Similarly, a wide variety of stent configurations are workable and most of these can be formed into useful antennas.

Example 6

The antenna was constructed with the support of the sinusoidal (or crenellated) loop, supported by an extension of the ends of the loop, at right angles to the main plane of the loop, as parallel wires also contained in the silicone polymer create a capacitance in series with the loop.

The length of the parallel wires was made in 3mm so that when the self inductance of the loop generates an impedance to the oscillating current in the loop wire, it is matched by the impedance of the capacitance and the assembly then causes a tank circuit oscillation with a large increase in available voltage.

The device was tested with radiation at 0.86 GHz and gave 2 volts and 800 microwatts when immersed in blood medium.

Example 7

The antenna of Example 6 was used to power a Sharp SM5K3 microprocessor so that the incorporated analog to digital (A/D) converter could be used to input the low frequency signal of an ECG which was simulated on a 1 Hz triangle wave in the blood medium. The output of the microprocessor generated a one bit signal when it had power and had detected the simple signal.

Example 8

The second A/D converter of the microprocessor was used to measure pH by incorporating a miniature pH glass electrode and silver/silver chloride reference electrode . The pH was changed by addition of acid to the blood medium and the microprocessor registered this change by an output of changing output.

Summary

Examples 5 to 8 illustrate that a medical appliance can be fabricated which will receive radiation with a frequency between 0.5-5 GHz.

Description of the Drawings

The invention will now be further illustrated with reference to the accompanying drawings in which:

Figure 1 is functional block diagram of a wireless electrical muscle stimulation system embodying the first two aspects of the invention;

Figure 2 is a functional block diagram of a receiver and activator for a wireless FES system;

Figure 3 is a block diagram of a second embodiment of the first two aspects of the invention;

Figure 4 is a block diagram showing the construction of a digital form of the receiver activator;

Figure 5 is a block diagram of a system for providing feedback for artificial stimulation;

Figure 6 is a conceptual view of a third embodiment of the first two aspects of the invention;

Figure 7 is a side perspective view of an embodiment of the third aspect of the invention.

As introductory comment to the description of the drawings in Figures 1 to 6, the antenna based device is a receiver and addressable activating device to enable electrical stimulation of muscles (skeletal, smooth or cardiac) is described below. This receiver is constructed to enable it to be implantable within the body of the subject, and in practice a plurality of receivers would be implanted at different locations in the body to stimulate different muscles. The receiver derives its energy for operation from electromagnetic radiation emanating from a primary controller. The primary controller also provides, by way of the electromagnetic signals having a frequency between 0.5 to 5 GHz, commands to control the receiver and activator so as to produce appropriate electrical stimulation signals to the muscle.

To enable a wireless FES system to operate with multiple receivers/activators stimulating different muscles and to be controlled by a single primary controller, it must be able to control each receiver/activator individually. To achieve this, each receiver can be constructed to respond only to a certain form of signal issued from the transmitter. There are various ways in which that can be implemented, comprising a digital addressing scheme and a frequency coded addressing scheme. Because the system is wireless, and both power and control signals are transmitted from the primary controller to the multiple receivers by way of the stated electromagnetic radiation, numerous receiver/activators can be controlled using a single primary controller without the difficulties associated with implanted or even external wiring, such as wires passing through jointed areas in the body.

Each receiver comprises an antenna, also implanted, tuned to receive the electromagnetic radiation from a primary controller which may be worn on or about the body of the subject. As indicated, the high frequency electromagnetic signals are in the range of 0.5 to 5 GHZ. A portion of the signal energy is utilised to provide electrical power to the activator circuitry, and another portion of the signal is decoded to provide control information such as the address of the receiver/activator and the shape and size of pulse to be provided at the output electrode.

This receiver/activator device is preferably encapsulated using a biocompatible resin such as silicone. The output of the activator is a stimulating electrode which is preferably constructed of titanium or a similar biocompatible conductive material. The electrodes are self attaching or may be sutured to the muscle, and can be constructed of a form which are known in the art. The size of each output electrode may be of the order of 2 mm to 20 mm. If the muscle to be stimulated is located relatively deep inside the body, the receiving portion of the device, comprising the antenna, can be located near the surface and provided with a short wire link to the activating site, however it is preferable to select a frequency of the electromagnetic radiation that permits the entire device to be close to the nerve site being stimulated using electrodes on the surface of the device or very short leads to the stimulating electrodes

It may be advantageous to provide a coating or patch of an anti reflection material (suitable for the electromagnetic frequency utilised for communication between the transmitter and receiver) positioned on the skin of the subject where the receiver is located, if it is desirable to reduce the required level of radiated energy such as for the abdomen area.

Turning to the drawings, Figure 1 is a functional block diagram of a primary controller 2 and receiver 10 system. The receiver and activator device 10 is also illustrated in block diagram form in Figure 2. The device 10 includes a dipole antenna 12 which is constructed to receive electromagnetic signals radiated from the primary controller 2. Data signals and power is transmitted by the primary controller 2 at frequencies which are in the range of 0.5 to 5 GHz. The dipole antenna 12 can be constructed from a suitable conductive material, such as titanium, or an integrated circuit die, and may have the dimensions of, for example, 8 mm length, 4 mm width and 2 mm depth. The signals received by the antenna are passed to passive demodulating circuitry 14 of known construction. Signals of one frequency, F_1, are thereby demodulated to provide an electrical power source for the activator circuitry 22, 24, 26. The electrical power provided by the output of demodulator 14 is used to charge the capacitive storage element 16.

A second frequency, F_2, produced by the primary controller 2 is the carrier frequency which carries information responsible for addressing and controlling the specific receiver/activator device 10. Passive filtering circuitry 18 of conventional design can be used to isolate the control signals at carrier frequency F_2, which are then demodulated. The

control signals provide by the output of the demodulator 20 are passed to the activator circuitry 22, 24, 26.

The activator circuitry portion of the device 10 comprises a digital register and comparator 22 which is able to decode the address portion of the transmitted data. The address is provided to enable selection of one single activation device or a group of devices, and a given activator may be required to be able to decode more than one address (eg one address for the particular device itself and one address for each of group of devices it may belong to). The second burst of pulses is decoded by the devices selected according to the address information, and this provides the information for that device regarding the shape and size of the pulse to be generated at the stimulating electrode. The pulse according to the received data is thus generated by the pulse generator 24, which can also be of conventional form, appears at the electrode plate 26 to stimulate the tissue it is embedded in. The electrode plate may be physically next to the rest of the receiver/activator device 10, or may be a short distance away and coupled thereto by an insulated multistrand stainless steel wire, for example. The device 10 is designed to deliver a variable current from the output electrode 26. This provides the flexibility for use in various different applications. The shape and rate of the train of pulses generated by the pulse generator is dependent on the transmitted signals, and can be dynamically controlled by the primary controller 2 to meet the muscle recruitment requirements. This flexibility is useful in order to be able to have a control over the recruitment of motor units. This is a feature that the existing stimulators have not been able to offer.

In Figure 3, the appropriate activating device is addressed by a choice of modulating tones which is decoded by means of band pass filters 28. In this case, the duration of the tone can be used to determine the width of the pulse to be output by the pulse generator 24. The pulse then appears at the electrode plate 26 and drives a current stimulus through the tissues it is embedded in. Once again, the electrode plate may be physically next to the remainder of the activator device or may be a short distance away and coupled thereto, for example, by an insulated multistrand SS wire.

Figure 4 illustrates in block diagram form a digital implementation of the receiver/activator 30, in which the functions of the signal filtering, demodulation, address decoding and pulse generation are all performed by a single integrated microprocessor and A/D converter

circuit 34. The power for the circuit 34 is provided by the power supply circuit 32, which operates in the same manner as described hereinabove, deriving usable electrical current from the electromagnetic radiation received at the receiver antenna 12. The functions of the microprocessor and A/D converter circuit are controlled by, for example, micro-coded computer program instructions in a known way. The stimulations pulses to the electrodes 26 are driven directly from the integrated circuit, and this diagram also illustrates the possibility of driving: more than one electrode from a single receiver.

Features of the device described herein include the simple construction which makes it robust and immune to the traumatic environment existing inside the body. There are no coils in the device since inductive coupling is avoided. There are no chemical reactions which is a problem in devices which have charge storage bimetallic capacitors. Lengthy wires are not required, which makes the surgical implantation procedures very simple. The device characteristics do not change if there is tissue growth, and a controllable pulse duration and stimulating current is provided for. This is useful in case where the muscle characteristics were to change whether over a long duration of time (eg through aging) or over a short duration (such as through muscle fatigue).

Because the system of the present invention does not require direct wired connections from the primary controller, numerous antenna based devices (eg stimulator devices) can be implanted without the difficulties associated with the wires bypassing joints in the subject. For example, it is estimated that a minimum of perhaps 50 separate artificial stimulators would be required to fully restore a walking function in a subject with disabled motor functions to the legs, and wires to that many stimulator sites would be very problematic. The present invention provides a system which can, however, easily accommodate that number of receiver/activators, with each individually addressable or addressable in selected groups. For example, with addressing of the receivers by respective digital codes, an eight bit code would enable selective activation of 256 devices and/or groups of devices.

In conjunction with FES stimulation, one further preferred aspect of the present invention also envisages a system which comprises an EMG recorder, an intelligent signal processor and an artificial stimulation controller. The purpose of this overall system is to be able to control the muscle stimulation pattern in order to provide near natural muscle contraction

for subjects with neuromotor control disorder. As such this embodiment incorporates the following features:

(a) EMG measurement from the muscles under stimulation to provide feedback for controlling the artificial stimulation;

(b) processing the EMG measurements using neural network processing to extract information relating to muscle fatigue and force of muscle contraction.

(c) the ability to control the muscle stimulation based on the muscle fatigue status and the net force of contraction being produced by the muscle.

The above features can be implemented in the following manner:

(a) Neural Networks and Time frequency atoms have been used in past to analyse EMG. (Englehart K et al, "Classification of Myoelectric Signal Burst Patterns Using A Dynamic Neural Network", IEEE 1995; Hiraiwa A et al, Shimohara K and Tokunga Y, "EMG Pattern Analysis and Classification by Neural Network" IEEE 1989; Jang GC, Cheng FHY, Lai JS and Kuo TS "Using Time Frequency Analysis Technique in the Classification of Surface Emg Signals", IEEE 1994). The present system utilises similar techniques to analyse EMG of the FES stimulated muscles for the purpose of having a closed loop FES system.

(b) During a training phase which is performed under supervision, a fixed stimulation pattern is applied to different electrodes in the same muscle. EMG recordings are memorised by the neural network against the muscle contraction pattern. The system learns the correlation of the EMG signal, force and fatigue. Fatigue is also taught to a parallel system with the help of the spectrum of the signal.

(c) Thereafter, the system stimulates the same muscle with the help of different pulse shapes and amplitudes and records the force of contraction. The system is self learning and this can continue even when the stimulating device is implanted. The system incorporates nested neural networks. The network learns the correlation between time, wave shape and strength of contraction.

(d) The trained system receives the EMG signal from the muscles being stimulated. The system works in a closed loop and with the help of training, it correlates time

EMG wave shape and spectrum with force of contraction and fatigue. The system then changes the pulse shape and rate of muscle stimulation in order to achieve a constant muscle contraction. The system is thus able to predict and compensate for the muscle fatigue. By suitably selecting a various different sets of electrodes in the same muscle, motor recruitment can therefore be altered and muscle fatigue prevented or reduced.

An example of an implementation of such a system 40 is illustrated in Figure 5. A stimulation controller 42 is used to artificially stimulate the subject's muscle 54 by way of FES electrodes 52 in order to achieve muscle contraction in the subject. EMG sensors 48 measure EMG feedback signals from the muscle, which are passed to an analyser circuit 46 and thence to a neural network processor 44. The neural network processor 44 provides electrical feedback to the stimulation controller 42 according to discerned muscle fatigue, etc. A joystick 50 or the like, under control of the subject, can provide physical feedback signals indicative of, for example, muscle contraction. The above described system thus enables a technique for processing surface EMG using intelligent signal processing techniques incorporating Neural Networks. The technique extracts information related to the status of muscle fatigue and force of the stimulated muscle. The system can therefore provide information related to change in motor recruitment and stimulation in order to maintain constant force of contraction and prevent fatigue. It can also analyse the need by the subject to increase or decrease the force of contraction of any muscle.

With reference to figure 6, the primary controller emits a signal to an implanted device in a leg. The implanted device takes the transmitted signal, decodes it, sends out pulses for muscle stimulation as specified by the signal regulating commencement time, pulse width, pulse frequency and number of pulses. As shown the device also comprises a sensor to measure characteristics such as EMG, pH, and muscle dimensions. It then transmits data to the primary controller. In this way, the system provides a remotely powered device that can be instructed to stimulate muscles and also monitor the state of the muscles.

The medical appliance 110 in Figure 7 has the basic elements of a known stent, that is, a spring 111 which is attached to a support 112. In this case, the support 112 is a structure capable of incorporating the elements of a monitoring device.

Due to the function of the spring 111 as an aerial for the monitoring device which is incorporated into the support 112, the amplitude of the sinusoidal pleats is kept small enough so that there is not a great deal of overlap between the loops of the spring in the stent. This prevents overlap of the electromagnetic fields generated by these individual loops.

The support 112 may therefore be at least substantially encapsulated in a biocompatible material, such as a suitable epoxy or the like. The sensors of the monitoring device may be constructed from a suitable biocompatible conductive material, such as titanium.

The medical appliance 110 in Figure 7 is shown in its expanded form. When the medical appliance 110 is being inserted into place, the spring 111 will be in a collapsed form (not shown) to allow for easier insertion.

It is to be understood by those skilled in the technology that many variations or modifications in details of design or construction may be made without departing from the essence of the present invention. Therefore, the invention should be understood to comprise all such variations and modifications within its scope. Further, whilst the applications of the invention has been described in relation to the human body, they are equally applicable to other living bodies such as animals.

The word 'comprising' as used in this description does not limit the invention claimed to exclude any variants or additions.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A system for transmission of power and/or information between a first location external of a living body and a second position internal of the living body which comprises:

   (a) a primary controller comprising a power source and a transmitter locatable at the first location; and

   (b) an antenna based device locatable at the second position to receive an output from the transmitter,

   wherein the power source is adapted to emit high frequency electromagnetic radiation between 0.5 to 5 GHz.

2. A system according claim 1 wherein the power source in the primary controller is adapted to emit high frequency electromagnetic radiation between 0.8 to 2.5 GHz.

3. A system according to either of claims 1 or 2 wherein the antenna format of the antenna based device is a planar omnidirectional format that is integrated into the construction of the antenna based device.

4. A system according to any of claims 1 to 3 wherein the antenna format of the antenna based device is a simple dipole, a loop with or without crenellations, or a microstrip antenna including slot and patch formats.

5. A system according to any of claims 1 to 4 wherein the primary controller further comprises other devices.

6. A system according to claim 5 wherein the other device in the primary controller is a receiver to receive data from the implanted device.

7. A system according to any of claims 1 to 6 wherein the antenna based device further comprises means to monitor predetermined conditions adjacent the antennae based device and to emit signals representative of one or more of these conditions to be received by the primary controller.

8. A system according to any of claims 1 to 7 wherein the antenna based device further comprises means to generate pulses of current.

9. A system according to any one of claims 1 to 8 wherein the antenna based device is a medical appliance.

10. A system according to claim 9 wherein the antenna based device is a stent.

11. A method for transmitting power and/or information between a first location external of a living body at which a primary controller comprising a power source and a transmitter is located, and a second location inside the living body at which an antenna based device is located, the method comprises the steps of:

(a) generating high frequency electromagnetic radiation between 0.5 to 5GHz from the power source and emitting that radiation from the transmitter of the primary controller; and

(b) receiving the radiation at the antenna based device.

12. A method according to claim 11 wherein the high frequency electromagnetic radiation in step (a) is 0.8 to 2.5 GHz.

13. A method according to either of claims 11 or 12 wherein the method comprises the further steps of:

(c) powering the antenna based device with the radiation; and/or

(d) causing the antenna based device to generate and emit pulses of current; and/or

(e) monitoring predetermined conditions adjacent to the antenna based device and emitting signals representative of one or more of these conditions to be received by the primary controller.

14. A medical appliance comprising a spring-based stent incorporating a monitoring device wherein the spring of the stent acts as the aerial for the monitoring device and wherein the medical appliance is capable of receiving electromagnetic radiation with a frequency between 0.5 to 5 GHz.

15. A medical appliance according to claim 14 wherein the monitoring device is located in the support of the stent.

16. A medical appliance according either of claims 14 or 15 wherein the monitoring device further comprises means to monitor predetermined conditions in the vicinity of the medical appliance.

17. A medical appliance according to any one of claims 14 to 16 wherein the monitoring device works in conjunction with a primary controller.

18. A medical appliance according to claim 17 wherein the monitoring device further comprises means to emit signals representative of one or more of these conditions to be received by the primary controller.

19. A medical appliance according to either of claims 17 or 18 wherein the primary controller is separate and located outside the body in which the stent is implanted.

20. A medical appliance according to any one of claims 17 to 19 wherein the primary controller is a power source for the monitoring device.

21. A medical appliance according to claims 17 to 20 wherein the primary controller is adapted to emit high frequency electromagnetic radiation between 0.5 to 5 GHz.

22. A medical appliance according to any one of claims 17 to 21 further comprising an intermediate implant which relays the power and instructions from the primary controller device to the medical appliance.

23. An artificial muscle stimulation system comprising:

(a) at least one stimulating device for providing artificial electrical stimulation to a muscle under control of a primary controller capable of transmitting high frequency electromagnetic radiation between 0.5 to 5 GHz;

(b) an electromyogram sensor for measuring electromyogram signals from the muscle during stimulation; and

(c) a neural network processor coupled to receive the measured electromyogram signals to extract information regarding force of contraction and fatigue of the muscle;

wherein the primary controller is coupled to an output of the neural network processor to control said artificial electrical stimulation based on said extracted information.

24. A method for implementing an artificial stimulation system which comprises an electromyogram recorder, an intelligent signal processor and an artificial stimulation controller capable of transmitting high frequency electromagnetic radiation between 0.5 to 5 GHz comprising the steps of:

(a) performing a training phase under supervision wherein a fixed stimulation pattern is applied to different electrodes in the same muscle; electromyogram recordings are memorized by the neural network against the muscle contraction pattern; and the system learns the correlation of the electromyogram signal, force and fatigue;

(b) thereafter, recording the force of contraction when the same muscle is stimulated with different pulse shapes and amplitudes;

(c) correlating the time electromyogram wave shape and spectrum of electromyogram signals received from the muscle being stimulated with force of contraction and fatigue; and

(d) changing the pulse shape and rate of stimulation in order to achieve a constant muscle contraction.

25. A method for transmitting information from a primary controller to an antenna based device comprising the step of using a power signal as a carrier for the information signals.

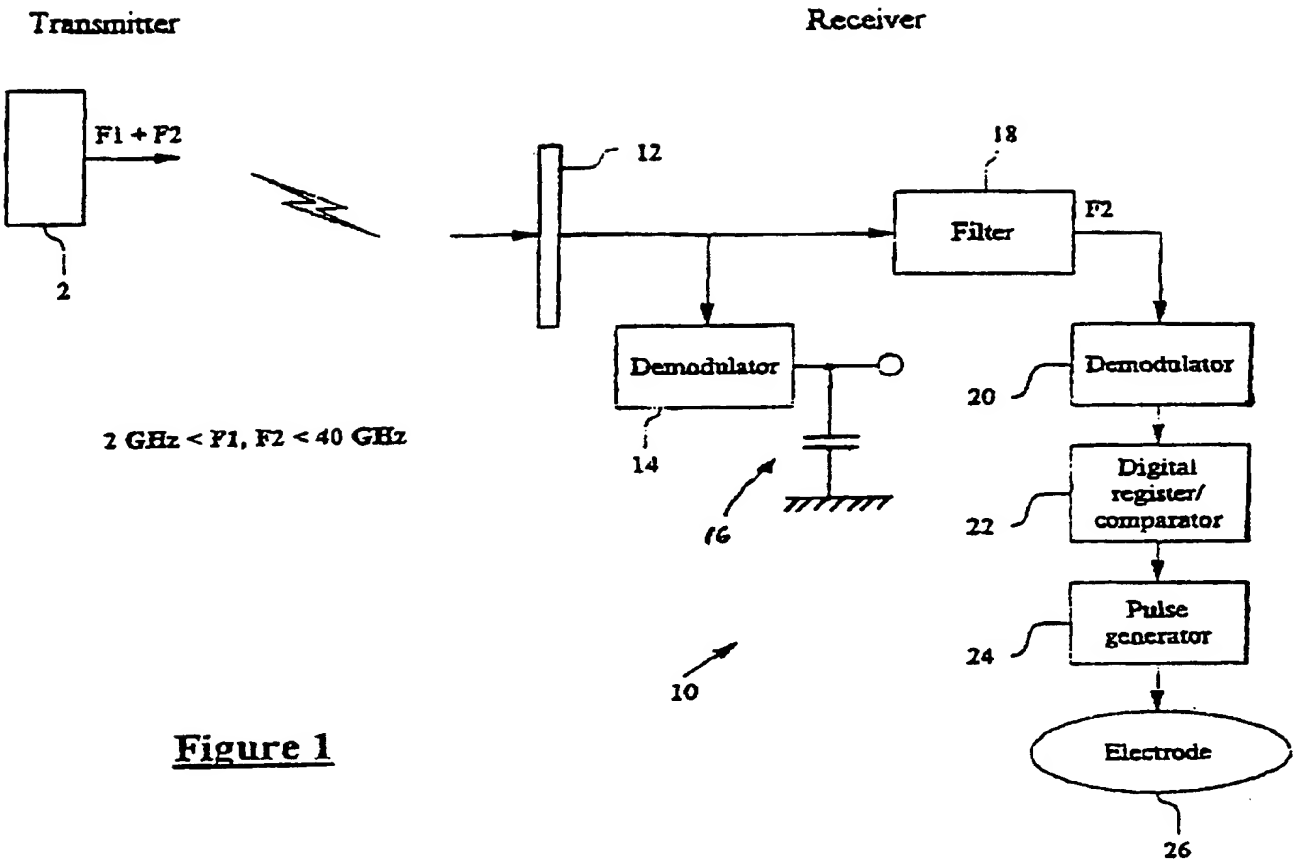

Figure 1

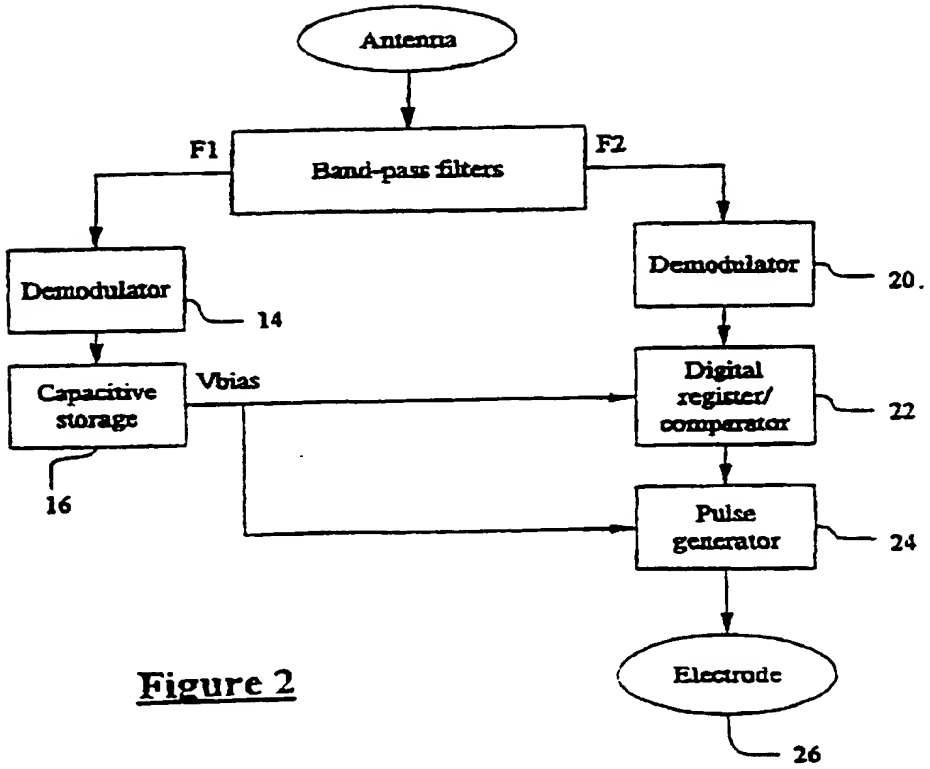

Figure 2

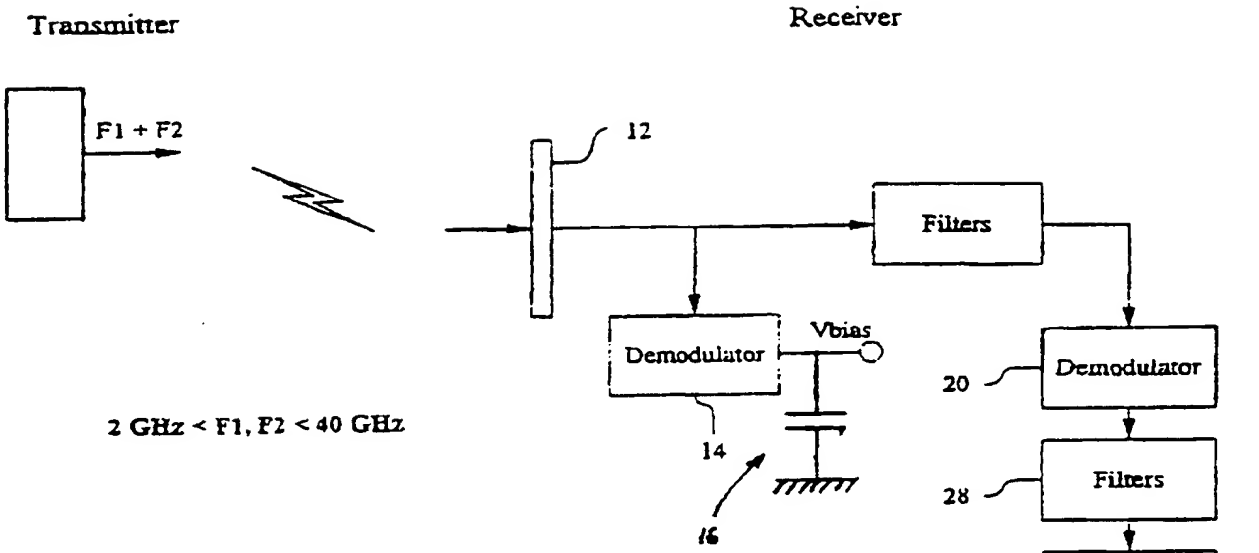

Figure 3

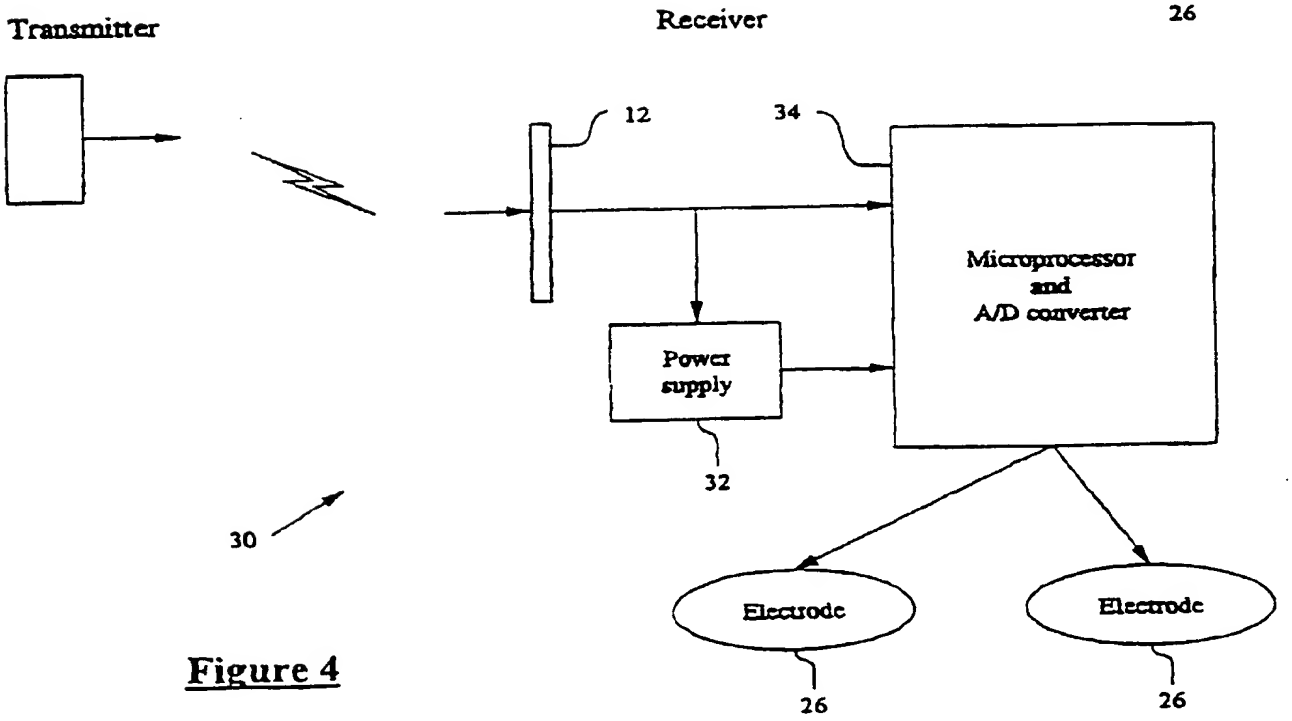

Figure 4

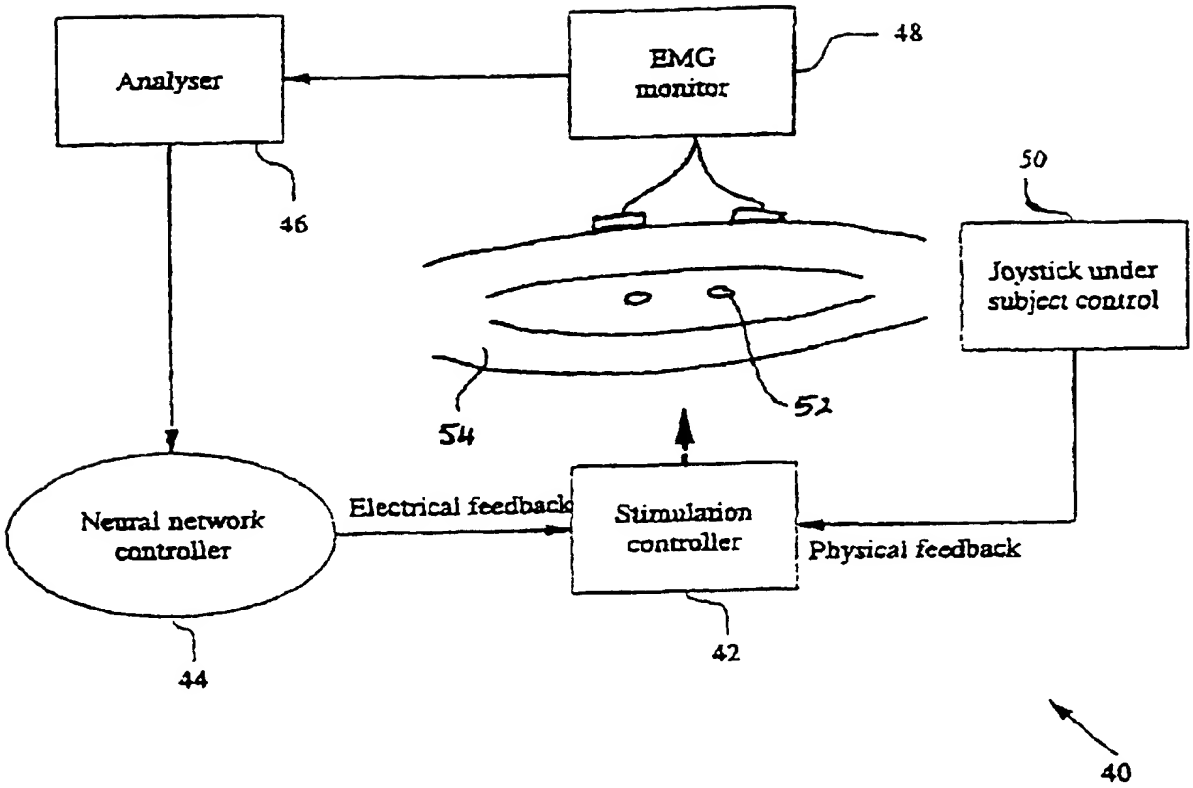
Analyser
EMG monitor
48
46
50
Joystick under subject control
52
54
Neural network controller
Electrical feedback
Stimulation controller
Physical feedback
44
42
40

Figure 5

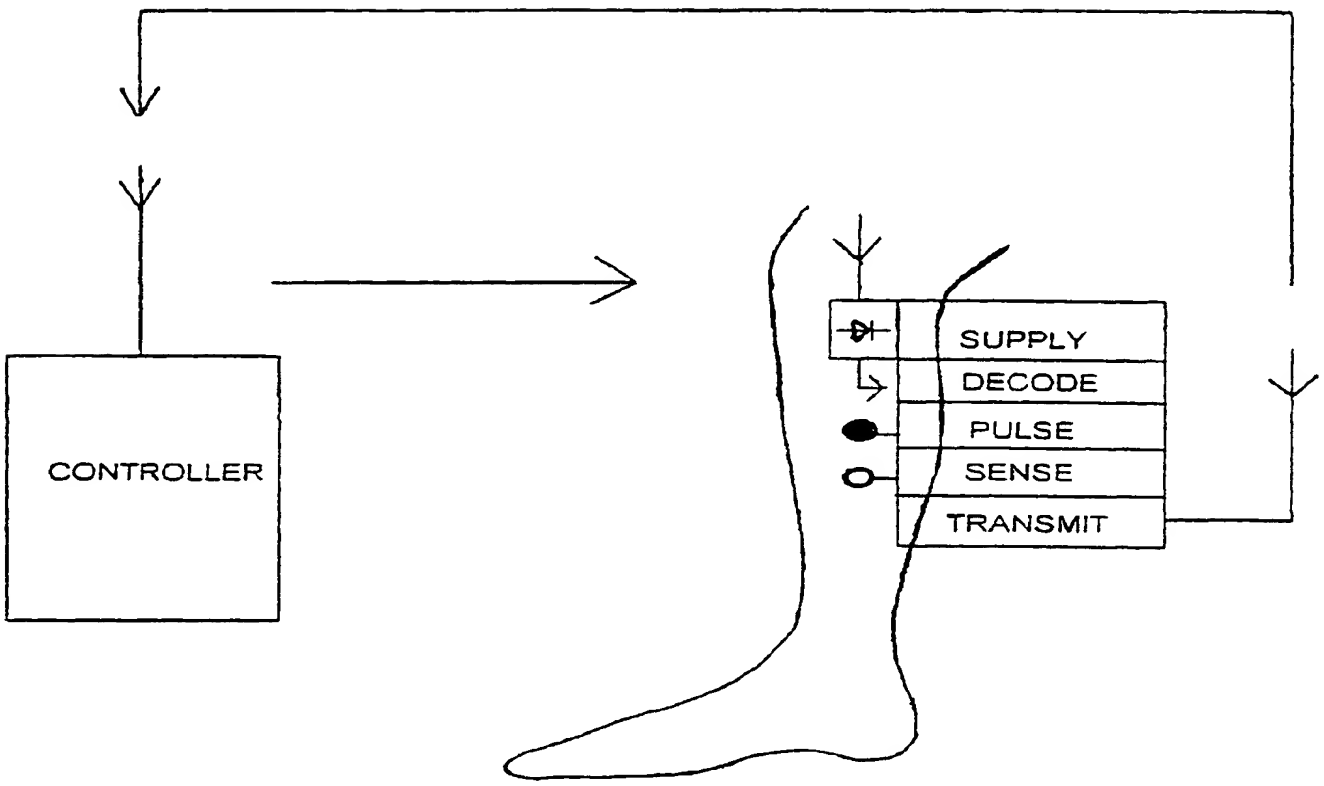

FIGURE 6

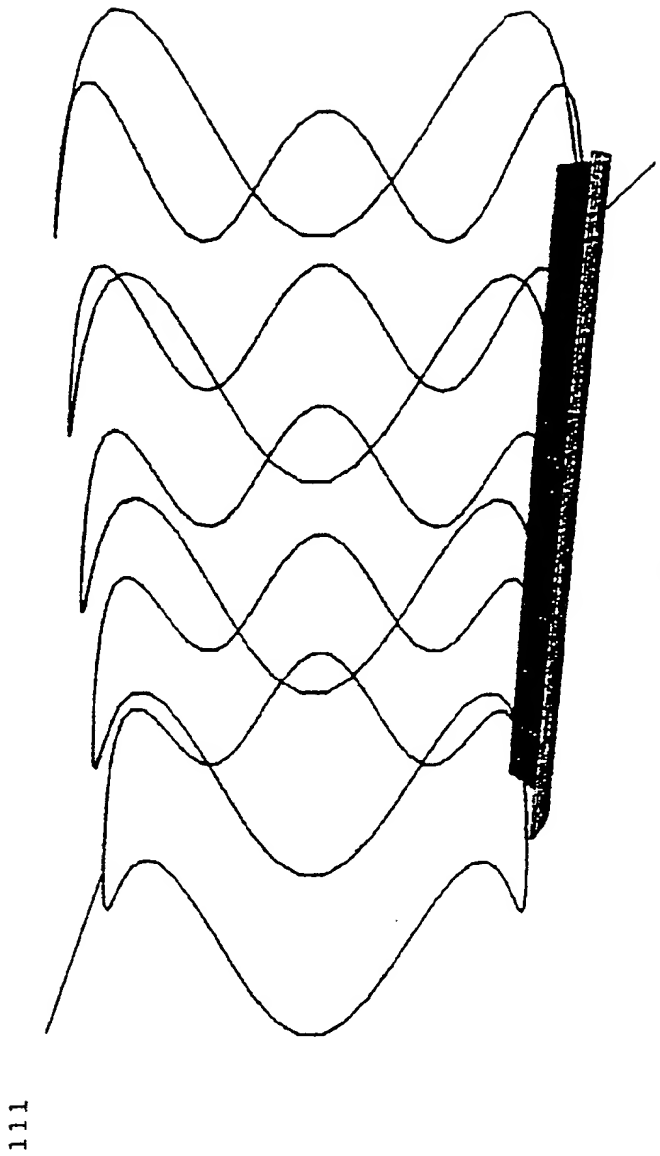

FIGURE 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00726

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 5/05, A61F 2/04, A61F 2/48, A61M 29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61#

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT, IBM Patent Database

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98/29030 (Johnson & Johnson Research) 9 July 1998 See whole document.	1-24
A	US 5735887 (Barreras, Sr. et al.) 7 April 1998 See whole document.	1-24
A	US 5769875 (Peckham et al.) 23 June 1998 See whole document.	1-24

☐ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
5 October 1999

Date of mailing of the international search report
11 OCT 1999

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00726

Box 1 Observations where certain claims were found unsearchable (Continuation f item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: **25**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

The scope of the claim is indeterminate.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00726

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member		
WO 98/29030	AU 53386/98	CA 2247943	EP 904009
	IL 125932		
US 5769875	US 5776171		

END OF ANNEX